UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
KENEDY, ANDREW A

ART UNIT	PAPER NUMBER
1631	14

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/964,059	FRUDAKIS, TONY NICK
	Examiner	Art Unit
	Andrew A. Kenedy	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-45_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-45_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____ .

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)
since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.
37 CFR 1.78.

    a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific
reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _14_ .

4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis

for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than year prior to the date of application for patent in the United States.

Claim 1-2 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Vijg et

al. (US 6007231 A).

Vijg et al. teaches a method and a computer-usable storage medium containing computer-

readable program code for processing gene sequence data and haplotyping comprising reading,

by the computer, gene sequence data corresponding to a gene sequence and coding sequence data

corresponding to a plurality of coding sequences within the gene sequence; identifying, by the

computer following a set of primer selection rules, primer pair data within the gene sequence

data, the primer pair data corresponding to a pair of primer sequences for one of the coding

sequences, the set of primer selection rules including a first rule specifying that the primer pair

data be obtained for a predetermined annealing temperature, and a first rule further specifying

that each primer sequence have a length that falls within one or more limited ranges of

acceptable lengths; storing the primer pair data; repeating the acts of identifying and storing such

that primer pair data are obtained for each sequence of the plurality of coding sequences at the

predetermined annealing temperature; and simultaneously amplifying the plurality of coding

sequences in gene sequences from three or more individuals at the predetermined annealing

temperature using the identified pairs of primer sequences, such that a plurality of amplified

coding sequences from the three or more individuals are obtained (see at least Fig. 6A and 6B;

column 3, line 30 through col. 4, line 33; and col. 6, lines 12-62). Note that while Vijg et al. do

not directly state that their method is applied to three or more individuals, they do state that their

method obviates the large-scale genotyping problem of "a large number of individuals to be

tested and when more than one gene is tested simultaneously in the same TDGS test" (col. 3,

lines 41-43; and col. 5, lines 23-25). Predating Vijg et al., Perlin (US 5580728 A) describes a

simultaneous sequence amplification method for genotyping, wherein Perlin states that by large-

scale genotyping, what is meant is "hundreds or thousands of individuals" (col. 3, lines 55-57).

As such, by stating "a large number of individuals to be tested...simultaneously in the same

TDGS test", Vijg et al. can be fairly interpreted to mean simultaneous amplification of sequences

from three or more individuals.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

Claim 3, 17 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Vijg et al. (US 6007231 A) in view of Vijg et al. (US 5814491 A).

Vijg et al. (US 6007231 A) is applied as above.

Vijg et al. (US 6007231 A) does not teach the set of primer selection rules as including a

second rule specifying that a single primer pair be identified for two or more coding regions if

they are sufficiently close together.

Vijg et al. (US 5814491 A) teaches a method of processing gene sequence data

comprising a primer selection rule specifying that a single primer pair be identified for two or

more coding regions if they are sufficiently close together (col. 6, lines 21-26).

It would have been obvious for one of ordinary skill in the art to add a second primer

selection rule to the primer selection rules of Vijg et al. (US 6007231 A), specifying that a single

primer pair be identified for two or more coding regions if they are sufficiently close together,

since using a single primer pair for two or more coding regions sufficiently close together will

reduce the overall number of amplicons to be amplified in simultaneous/multiplex PCR

reactions, which is advantageous according to Vijg et al. (US 5814491 A) who teaches that for

multiplexing, "limitations to primer choice, with total genomic DNA as template, are the reasons

why multiplex groups are usually small (typically less than 5 fragments)" (col. 4, lines 19-22).

Claims 4 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vijg et

al. (US 6007231 A), in view of Chin et al. (US 6470277 B1).

Vijg et al. (US 6007231 A) is applied as above.

Vijg et al. (US 6007231 A) does not teach the limitations that gene family data associated

with the gene sequence is read by the computer, and the set of primer selection rules includes a

second rule specifying that the primer pair data be excluded from the gene family data.

Chin et al. teaches a method of processing gene sequence data comprising the reading of

gene family data associated with a gene sequence by the computer and excluding primer pair

data from the gene family data (see at least Fig. 7; col. 2, lines 20-33; col. 14, lines 9-26; and col.

19, lines 39-56). It would have been obvious to one of ordinary skill in the art to incorporate the

computerized reading of gene family data associated with a gene sequence into the method of

Vijg et al. (US 6007231 A) described above, while excluding primer pair data, since the reading

of gene family data can be used for "identifying genes which might trigger, prevent, ameliorate,

or somehow affect a variety of diseases or physiological states" (col. 1, lines 33-36), while the

reading of primer pair data (i.e., primer sequence and primer annealing temperature) per se does

not contribute to the identification of disease genes and their associated

mutations/polymorphisms in the same way that gene family data does, that is, through textual

analysis to extract disease-related information and correlations from a pre-existing

knowledgebase, rather than through physical analysis as when utilizing primers in a laboratory

test to acquire new information through direct experimentation.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vijg et al. (US

6007231 A) and Vijg et al. (US 5814491 A), in view of Chin et al. (US 6470277 B1).

Vijg et al. (US 6007231 A) and Vijg et al. (US 5814491 A) are applied as above.

Vijg et al. (US 6007231 A) and Vijg et al. (US 5814491 A) do not teach the limitations

that gene family data associated with the gene sequence is read by the computer, and the set of

primer selection rules includes a second rule specifying that the primer pair data be excluded

from the gene family data.

Chin et al. teaches a method of processing gene sequence data comprising the reading of

gene family data associated with a gene sequence by the computer and excluding primer pair

data from the gene family data (see at least Fig. 7; col. 2, lines 20-33; col. 14, lines 9-26; and col.

19, lines 39-56). It would have been obvious to one of ordinary skill in the art to incorporate the

computerized reading of gene family data associated with a gene sequence into the methods of

Vijg et al. (US 6007231 A) and Vijg et al. (US 5814491 A) described above, while excluding

primer pair data, since the reading of gene family data can be used for "identifying genes which

might trigger, prevent, ameliorate, or somehow affect a variety of diseases or physiological

states" (col. 1, lines 33-36), while the reading of primer pair data (i.e., primer sequence and

primer annealing temperature) per se does not contribute to the identification of disease genes

and their associated mutations/polymorphisms in the same way that gene family data does, that

is, through textual analysis to extract disease-related information and correlations from a pre-

existing knowledgebase, rather than through physical analysis as when utilizing primers in a

laboratory test to acquire new information through direct experimentation.

Claim 5-6 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vijg

et al. (US 6007231 A), in view of Giordano et al. (US 5807681 A).

Vijg et al. (US 6007231 A) is applied as above.

Vijg et al. (US 6007231 A) does not teach sequencing the plurality of amplified coding

sequences to produce a plurality of nucleotide base identifier strings, wherein the plurality of

nucleotide base identifier strings includes nucleotide base identifiers represented by the letters G,

A, T, and C.

Giordano et al. (US 5807681 A) teaches a method of processing gene sequence data

comprising sequencing of amplified coding sequences to produce nucleotide base identifier

strings, wherein the nucleotide base identifier strings include nucleotide base identifiers

represented by the letters G, A, T, and C (see Fig. 2; col. 10, lines 20-27; col. 12, lines 30-41;

and col. 5, lines 54-67).

It would have been obvious for one of ordinary skill in the art incorporate the sequencing

of the amplified coding sequences to produce nucleotide base identifier strings represented by

the letters G, A, T, and C within the method of Vijg et al. (US 6007231 A), since Giordano et al.

teaches that for analyzing polymorphisms/mutations in amplified gene segments "one must still

sequence the sample segment...and the sequence of the segment must be compared to the

nucleotide sequence for the corresponding wild type in order to determine the exact location and

nature of the mutation, i.e., point mutation, deletion or insertion" (col. 12, lines 30-42).

Claims 7-13, 21-27, 29-34, and 36-41 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Vijg et al. (US 6007231 A) and Giordano et al. in view of Stanton Jr. et al.

(US 6401043 B1) and Stanton Jr. et al. (US 6475736 B1).

Vijg et al. (US 6007231 A) and Giordano et al. are applied as above.

Vijg et al. (US 6007231 A) and Giordano et al. do not teach the limitations of claims

7-13, 21-27, 29-34, and 36-41.

Stanton Jr. et al. (US 6401043 B1) teaches a method and encoded computer-readable

medium for processing gene sequence data and haplotyping by computer comprising reading a

plurality of nucleotide base identifier strings; positionally aligning a plurality of nucleotide base

identifier strings to produce a plurality of aligned nucleotide base identifier strings; comparing

aligned nucleotide base identifiers at each nucleotide base position of the plurality of aligned

nucleotide base identifier strings; at each nucleotide base position where a difference amongst

aligned nucleotide base identifiers exists: reading nucleotide base quality information associated

with the aligned nucleotide base identifiers where the difference exists, comparing the nucleotide

base quality information with predetermined qualification data, and if the quality information

meets the predetermined qualification data and is accepted, providing and storing resulting data

that identifies where the difference amongst the aligned base identifiers exists; wherein the

resulting data comprise SNP identification data; wherein, after providing and storing all resulting

data that identifies where the differences amongst the aligned nucleotide base identifiers exist, at

each nucleotide base position where a difference exists comparing the nucleotide base identifier

with a prestored nucleotide base identifier to identify whether the nucleotide base identifier is a

variant, and providing and storing additional resulting data that identifies whether the nucleotide

base identifier is a variant, wherein the additional resulting data comprises haplotype

identification data (see at least Fig. 5 and 7; col. 7, lines 34-50; col. 3, lines 8-49; col. 12, lines

14-18; col. 5, lines 12-42; col. 7, lines 51-59).

Stanton Jr. et al. (US 6401043 B1) does not teach the limitations of visually displaying,

from the computer, nucleotide base quality information for acceptance or rejection, and that the

nucleotide base quality information comprises one or more phred values.

Stanton Jr. et al. (US 6475736 B1) teaches a method of processing gene sequence data

and haplotyping comprising visually displaying, from the computer, nucleotide base quality

information for acceptance or rejection, and that the nucleotide base quality information

comprises one or more phred values (col. 66, lines 39-55).

It would have been obvious for one of ordinary skill in the art to incorporate the analysis

of sequence variations by alignment, comparison, qualification, and validation as taught by

Stanton Jr. et al. (US 6401043 B1) and Stanton Jr. et al. (US 6475736 B1) above, since Stanton

Jr. et al. (US 6401043 B1) teaches that a haplotyping method which allows "identification of

gene sequence variances within genes that may be involved in drug action is important for

determining whether a given drug or other therapy may be safe and effective in an individual

patient...[and] useful in connection with predicting differences in response to treatment and

selection of appropriate treatment of a disease or condition" (col. 2, lines 45-55), while Stanton

Jr. et al. (US 6475736 B1) teaches that use of a viewer on the computer allows one "to visually

inspect the data and verify variances" and that the use of the PHRED program to assign phred

values to DNA sequencing reaction results allows "the quality of DNA sequencing reactions [to

be] assessed automatically and numerically scored" and then easily analyzed for acceptability

based upon a predetermined phred quality score level (col. 66, lines 40-51).

Claims 14, 28, 35, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Vijg et al. (US 6007231 A), Giordano et al., Stanton Jr. et al. (US 6401043 B1), and Stanton Jr.

et al. (US 6475736 B1), in view of McKernan et al. or Dolfing.

Vijg et al. (US 6007231 A), Giordano et al., Stanton Jr. et al. (US 6401043 B1), and

Stanton Jr. et al. (US 6475736 B1) are applied as above.

Vijg et al. (US 6007231 A), Giordano et al., Stanton Jr. et al. (US 6401043 B1), and

Stanton Jr. et al. (US 6475736 B1) do not teach providing and storing a binary value of '0' for

those nucleotide base identifiers that are identified as variants and a binary value of '1' for those

nucleotide base identifiers that are not.

McKernan et al. (see at least col. 17, lines 48-51) and Dolfing (see at least col. 2, lines

43-55) both teach providing and storing binary values of '0' or '1' for positive (yes) and negative

(no) Boolean decisions.

It would have been obvious for one of ordinary skill in the art to provide and store binary

values of '0' and '1' for nucleotide base identifiers that are either identified as variants (yes) or not

(no), since McKernan et al. or Dolfing both independently demonstrate that binary values are

routinely assigned to Boolean operators such as 'yes' and 'no' when providing and storing these

type of answers made to queries contained within methods executed through computerized

algorithms.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Andrew A. Kenedy whose telephone number is 703-305-4842.

The examiner can normally be reached on Monday-Friday 9:00am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is 703-305-4842.

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800

AAK

Nov. 12, 2003